Axela, Inc.- dotLab mX

GENERAL DESCRIPTION:

The dotLab® mX System uses a novel, flow based Diffractive Optics Technology (dot®) to combine multiplex immunoassay formats with real time measurements. The result is a highly flexible, easy to use and low cost platform that can provide more informative immunoassays compared to traditional techniques. Together these features are designed to address the growing need for running routine, multiplex assays on a variety of crude biological samples. With the dotLab® mX System, researchers will have the abilities to qualify reagents during immunoassay development, develop novel diagnostic tests, or investigate disease biomarkers for potential clinical applications.

One of the key applications for the dotLab® mX System is the development of rapid diagnostic tests for infectious diseases which can be performed at the point of testing. The System is also well adapted to analyze fresh samples as they are acquired and can analyze intact pathogens eliminating sample preparation.

TECHNICAL DESCRIPTION:

Diffractive optics technology combines grating-based light diffraction and immobilized capture surfaces. Capture molecules are immobilized on an ordered pattern of lines that form a diffraction grating on the prism-shaped dotLab® Sensor. Diffraction beams are generated when the patterned molecules are illuminated with a laser. Binding of biomolecules to the patterned capture molecules increases the height of the surface pattern, producing an increased phase shift in the reflected beams, which in turn increases diffraction signal intensity that is detected in real time by a photodiode detector below the sensor. The laser beam doesn't pass though the bulk solution in the flow channel significantly reducing the effects of sample refractive index which allows for the direct analysis of crude biological samples. Its picomolar sensitivity and extended dynamic range of detection (> 7 logs) enable the analysis of both high and low abundance analytes without the need to perform sample dilutions. Finally, multiplex optical sensors have been created that can be customized by the user to analyze a multiple of biomarkers of their choice.

Tier Selection

Final tier assignment is based on overall product score.

Top Tier | Second Tier | Third Tier | Fourth Tier | Bottom Tier

RANKINGS

	Biological	Chemical	Radiological
FIELD USE System	Fourth Tier	N/A	N/A
MOBILE Laboratory	Second Tier	N/A	N/A
DIAGNOSTIC Laboratory	Top Tier	N/A	N/A
ANALYTICAL Laboratory	Top Tier	N/A	N/A

Survey Source

Vendor Supplied Information

CONTACT INFORMATION

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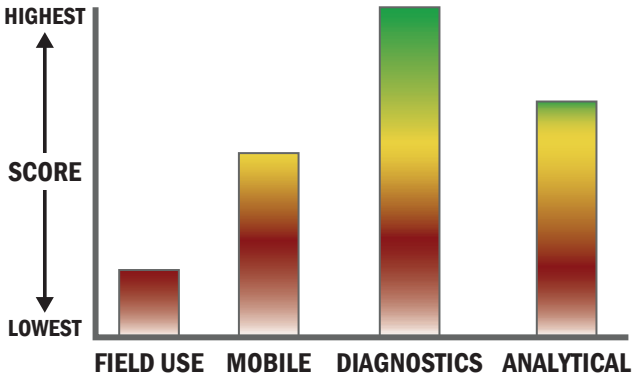
COST

- $73,500/system
- $5-$10/analysis

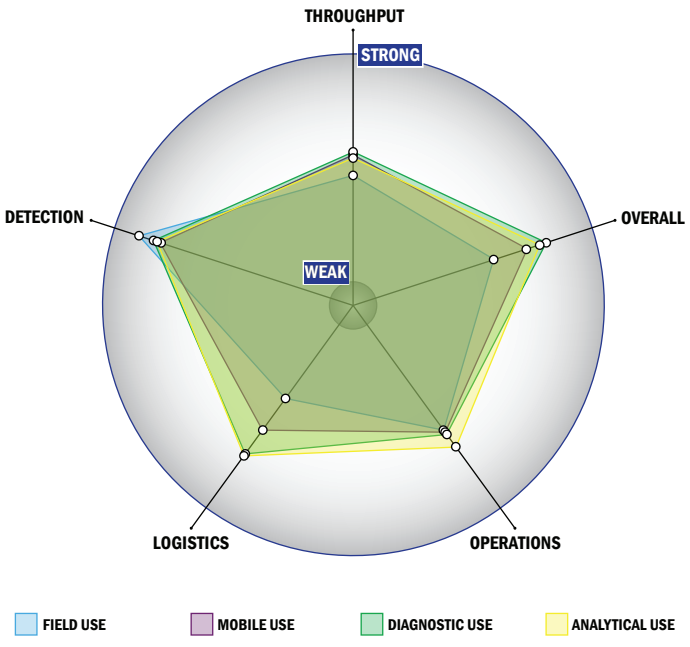
Scoring Analysis

System scores are compared across the four scenarios and ranked from highest to lowest.



Impact Chart

The Impact Chart is a spider graph representing specific categories and designed to give the reader a visual depiction of how a particular system is expected to operate across the four different scenarios. The score for each of the seven categories is presented as the percentage of the total possible score. Higher category scores extend the spokes of a graphic toward the outer edge of the chart. The area graphed for each of the four scenarios relates to how well the system performed in that scenario. Graphics for each of the four scenarios are super-imposed for ease of comparison.



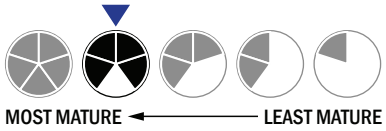
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- Multiple samples, multiple tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 4 solutions, buffer, eluents, and/or reagents
- 3 components
- Less than 5 minutes is required for set-up
- 3-5 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Wired connections are available
- System or device has 110V electrical requirement



Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at 4 °C
- Device or system has peak performance at normal relative humidity conditions
- Between 6 months and 1 year shelf life
- 5-10 years expected life
- Results can be viewed in real-time
- The system is not capable of autonomy
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

Detection:

- Not possible for the system to achieve 510K clearance
- Efforts are underway to achieve FDA approval
- Less than 10 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- Less than 1 ng per mL
- Manual kit not integrated with the system handles spore lysis